

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

G. W. ARU, LLC, *et al.*,

*

Plaintiffs,

*

v.

Civ. No. JKB-22-2636

W. R. GRACE & CO.-CONN.,

*

Defendant.

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* * * * *

MEMORANDUM

A trial in this action for patent infringement and false advertising is scheduled for May 2025.¹ (ECF No. 225.) In anticipation of that trial, both Plaintiffs and Defendant have filed Motions to Exclude, which seek to bar certain testimony proffered by the opposing side's putative experts. (ECF Nos. 238, 242.) The Motions are brought pursuant to Federal Rule of Evidence 702 and *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993).²

The Motions to Exclude are fully briefed, and no hearing is necessary. *See* Local Rule 105.6 (D. Md. 2023); *McKiver v. Murphy-Brown, LLC*, 980 F.3d 937, 961 (4th Cir. 2020). For the

¹ Earlier today, the parties filed a joint motion stipulating to a bench trial, rather than a jury trial, and requesting the extension of certain deadlines. (ECF No. 269.) The Court will address that motion separately. Herein, the Court refers to the factfinder as "the jury" but observes that nothing in this opinion would change if the factfinder at trial is the Court rather than the jury.

² Also pending before the Court are several Motions to Seal. (ECF Nos. 222, 251, 255, 259.) The Motions to Seal are unopposed, but the Court still has an independent obligation to ensure that the public right of access to the courts is protected. (ECF No. 81 at 2.) The Court has reviewed the Motions to Seal under the First Amendment standard. *See Gonzalez v. Cuccinelli*, 985 F.3d 357, 376 (4th Cir. 2021); *Doe v. Pub. Citizen*, 749 F.3d 246, 265 (4th Cir. 2014). The Motions to Seal do not in effect seek the wholesale sealing of documents, but instead seek only (1) to redact certain passages in the briefs and exhibits that reveal trade secrets or other confidential business information, such as pricing details and technical product specifications, and (2) to seal permanently the unredacted versions of those same materials. Under these circumstances, the Court concludes that the redactions are appropriately narrowly tailored to serve the parties' compelling interests in confidentiality, and that no less-restrictive alternatives are available. Accordingly, the pending Motions to Seal will be granted.

following reasons, Plaintiffs' Motion to Exclude (ECF No. 242) will be granted in part and denied in part, and Defendant's Motion to Exclude (ECF No. 238) will be denied.

The Court will begin by summarizing the parties' respective arguments in support of their Motions to Exclude. Next, the Court will review the applicable legal standards for evaluating proffered expert testimony. The Court will then turn to an analysis of the parties' respective Motions to Exclude.

I. POSITIONS OF THE PARTIES

A. Plaintiffs' Arguments

Plaintiffs G. W. Aru, LLC and Cochise Technology, LLC (collectively, "GWA") seek to exclude portions of two putative experts—Michael Harold and Kimberly J. Schenk—proffered by Defendant W. R. Grace & Co.-Conn. ("Grace"). (ECF No. 242.)

With respect to Dr. Harold, GWA attacks the testimony on three grounds. First, GWA argues that Dr. Harold's report misquotes the text of the patent-in-suit, U.S. Patent No. 11,224,864 (the "'864 Patent"), and that, because his analysis of "applicant admitted prior art" or "AAPA" (and the attendant issues of anticipation and obviousness) depend on that misquotation, his testimony on the question must be excluded. (ECF No. 242-1 at 8–10.) Second—according to GWA—Dr. Harold, in opining on the question of prosecution history disclaimer, mischaracterizes a statement that GWA employee Dr. Natalie Herring made during patent prosecution. (*Id.* at 11–12.) GWA also argues that Dr. Harold's opinion on prosecution history disclaimer should be excluded because the issue is a legal rather than a factual one. (*Id.* at 12 n.1.) Third, GWA seeks to exclude Dr. Harold from testifying on statistics, on the grounds that he is not qualified to opine on the subject. (*Id.* at 12–16.)

With respect to Ms. Schenk, GWA argues that she improperly relies on "selling, general,

and administrative” expenses—which the Court simply will refer to as “overhead” expenses³—in calculating the deductions from the damages that Grace would have to pay if found liable for false advertising. (ECF No. 242-1 at 17–20.) Grace should not be permitted to present evidence of overhead deductions, GWA contends, because it has failed to show “a direct nexus between those expenses and its sales of the falsely advertised Optimized CP®P.” (*Id.* at 18.)

B. Defendant’s Arguments

Grace’s Motion to Exclude seeks to preclude portions of the testimony of two of GWA’s putative experts, Christian Tregillis and Christopher Ehrhardt. In particular, Grace “requests that the Court (1) preclude Mr. Tregillis from presenting any opinion regarding unjust enrichment that includes sales to six refineries for whom there is no evidence that they saw any false advertisements, and (2) exclude Dr. Ehrhardt’s opinion that the noble metal distribution of every Optimized CP-P particle can be determined by testing only 12 particles.” (ECF No. 238 at 1.)

With respect to Mr. Tregillis, who is GWA’s putative damages expert, Grace argues that his testimony groundlessly assumes that Grace’s challenged advertisements affected the purchasing decisions at six refineries, despite Mr. Tregillis not citing any evidence that those six refineries actually received the advertisements in question. (ECF No. 239 at 6.) Without any evidence showing that Grace’s advertisements were causally connected to the sales at those refineries, Grace contends, Mr. Tregillis’s testimony is not adequately supported by facts and data, and presents a risk of unfair prejudice by “skew[ing] the damages horizon for the jury” toward a higher number. (*Id.* at 12 (quoting *Uniloc USA, Inc. v. Microsoft Corp.*, 632 F.3d 1292, 1320 (Fed. Cir. 2011).)

³ Unless otherwise noted, the Court’s references to “overhead” should be understood to be synonymous with what the parties refer to as “SG&A,” or “selling, general, and administrative expenses.” “SG&A” is not a new expression (the Court is aware of judicial usage of the term dating back to the 1980s), but it is a clunky one; for the purposes of this Memorandum, the more natural if slightly less precise term “overhead” will suffice.

With respect to Dr. Ehrhardt, a professor whom GWA plans to call to testify regarding patent infringement, Grace argues that his statistical analysis of testing of Grace's Optimized CPP (the allegedly infringing product) is hopelessly flawed. Dr. Ehrhardt analyzed the results of testing conducted by Dr Herring of approximately thirty individual CPP particles. (See ECF No. 253-2 ¶ 27.) To choose this sample size, he relied on a statistical "rule of thumb" that Grace dubs the "Rule of 12," which essentially provides that, under certain conditions, the margin of error for an estimate decreases rapidly until one reaches a sample size of twelve, and then decreases more slowly from that point onward. (ECF No. 239-6 at 21.) Grace argues that Dr. Ehrhardt's reliance on this rule is foreclosed by Federal Circuit precedent barring experts from relying on certain "rules of thumb"; that, even assuming the Rule of 12 is sometimes appropriate, Dr. Ehrhardt did not ensure that the necessary preconditions for applying the Rule of 12 were met; and that, in any case, the results in Dr. Ehrhardt's own analysis refute the Rule of 12. (ECF No. 239 at 13–17.)

II. LEGAL STANDARDS

Federal Rule of Evidence 702 provides that:

A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if the proponent demonstrates to the court that it is more likely than not that:

- (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue;
- (b) the testimony is based on sufficient facts or data;
- (c) the testimony is the product of reliable principles and methods; and
- (d) the expert's opinion reflects a reliable application of the principles and methods to the facts of the case.

This Rule vests in district courts an "indispensable . . . gatekeeping function in all cases in which expert testimony is challenged on relevance and/or reliability grounds." *Sardis v. Overhead Door Corp.*, 10 F.4th 268, 284 (4th Cir. 2021). This gatekeeping role is necessary to ensure that the jury is not presented with "junk science," *id.* at 275, because "[e]xpert evidence can be both

powerful and quite misleading,” *id.* at 284 (quoting *Daubert*, 509 U.S. at 592).

In acting as a gatekeeper, the Court must “determine whether the testimony has a reliable basis in the knowledge and experience of the relevant discipline.” *Sardis*, 10 F.4th at 282 (quoting *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 149 (1999)). To determine whether testimony is reliable, the Supreme Court has provided “four, non-exhaustive guideposts” for district courts to consider:

- (1) whether the expert’s theory or technique “can be (and has been) tested”; (2) “whether the theory or technique has been subjected to peer review and publication”; (3) “the known or potential rate of error” inherent in the expert’s theory or technique; and (4) whether the expert’s methodology is generally accepted in his field of expertise.

Id. at 281 (ultimately quoting *Daubert*, 509 U.S. at 593–94)). While these factors help structure the Court’s inquiry, they need not be applied or satisfied in every instance. *See Belville v. Ford Motor Co.*, 919 F.3d 224, 233 (4th Cir. 2019). Instead, the Court has “broad latitude” both in “decid[ing] how to determine reliability” and in “its ultimately reliability determination.” *Kumho Tire*, 526 U.S. at 142. In every case, however, the Court’s analysis must focus on “principles and methodology, not on the conclusions that they generate.” *In re Lipitor (Atorvastatin Calcium) Mktg., Sales Pracs. & Prods. Liab. Litig. (No II)*, 892 F.3d 624, 631 (4th Cir. 2018) (quoting *Daubert*, 509 U.S. at 595). Ultimately, the Court must ensure “that an expert . . . employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field.” *Kumho Tire*, 526 U.S. at 152.

While the Court’s gatekeeping role is essential, it is also limited. In evaluating a *Daubert* motion, the Court does not decide the ultimate believability or correctness of an expert’s opinion. “Vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible

evidence.” *Daubert*, 509 U.S. at 596. As a result, “the rejection of expert testimony is the exception rather than the rule.” *In re Lipitor*, 892 F.3d at 631 (citation omitted).

III. ANALYSIS

The Court will analyze each side’s Motion to Exclude in turn, starting with GWA’s.

A. Plaintiffs’ Motion to Exclude

1. Testimony of Dr. Harold

Grace intends to present the testimony of Dr. Harold, a professor of chemical and biomolecular engineering at the University of Houston. (ECF No. 180-37 at 5.) In his opening report, he concludes, upon his analysis of eight prior art references as well as the alleged AAPA, that the ’864 Patent is invalid on the basis of anticipation and/or obviousness. (See *id.* at 22–206.) He also concludes that the patent is invalid on the basis of indefiniteness and lack of enablement.⁴ (*Id.* at 206–216.)

i. Testimony on Applicant-Admitted Prior Art

GWA seeks to exclude Dr. Harold from testifying about anticipation or obviousness on the grounds of AAPA. Any admission made by an applicant or patentee in the prosecution history or specification as to the prior-art status of a reference is deemed to be binding on the patentee for purposes of determining validity in a subsequent proceeding. 3 Robert A. Matthews, Jr., *Annotated Patent Digest* § 15:60 (Mar. 2025); see also *Riverwood Int’l Corp. v. R.A. Jones & Co.*, 324 F.3d 1346, 1354 (Fed. Cir. 2003); *PharmaStem Therapeutics, Inc. v. ViaCell, Inc.*, 491 F.3d 1342, 1362 (Fed. Cir. 2007). Thus, to the extent GWA contends that the ’864 Patent is invalid on obviousness or anticipation grounds, the question of what admissions—if any—the patentee made during

⁴ The Court has already concluded that the ’864 Patent is not invalid for lack of enablement, (ECF No. 231 at 61), so the Court does not expect Dr. Harold to testify on that subject.

prosecution and in the specification is one of some consequence. Dr. Harold's report discusses numerous such statements. (*See generally* ECF No. 210-37.) The passage at issue here, which occurs in the specification of the patent-in-suit, is as follows:

Without wanting to be limited by the following theory applicants believe that the presence of the noble metal in the outer eggshell of a microsphere particle is sufficient to achieve an active combustion promoter. This is because the CO to CO₂ oxidation as catalyzed by a Group VIII noble metal is a very rapid, essentially instantaneous, reaction at the FCC regenerator temperatures of approximately 704° C. (1,300° F.) which is known as a diffusion limited or a mass-transfer limited reaction. Thus, the noble metal in the center of the particle is not active for CO to CO₂ oxidation as the reactant gases (CO and O₂) react before reaching this noble metal.

'864 Patent at 3:2–13.

In Dr. Harold's report, however, he misquotes the last sentence by changing "thus" to "further, it is known," so that the sentence reads: "*Further, it is known* the noble metal in the center of the particle is not active for CO to CO₂ oxidation as the reactant gases (CO and O₂) react before reaching this noble metal." (ECF No. 210-37 ¶ 65.) This misquotation occurs nine times in Dr. Harold's report. (*Id.* ¶¶ 65, 87, 178, 217, 258, 303, 348, 394, 440.)

This error is perplexing. Grace downplays it as an "inconsequential typographical error" (ECF No. 252-1 at 5), but the Court does not see it as quite so trifling. An inconsequential typographical error is writing that a *trail* in this case is scheduled for May, rather than a *trial*. It would be a remarkable incident indeed, however, if someone set out to type the word "thus" but, by pure fortuity, somehow accidentally typed "further, it is known" instead.

At a minimum, the Court of course must prevent Dr. Harold from presenting testimony that is indisputably incorrect. *See* Fed. R. Evid. 702(b) (expert testimony must be "based on sufficient facts or data"). Thus, Dr. Harold must not be permitted to present his misquotation of the '864 Patent to the jury as the truth. The question, however, then becomes how much of Dr. Harold's analysis is fatally tainted by this error. If all of his AAPA analysis is inextricably intertwined with

his erroneous understanding of the language of the '864 Patent, then all of that analysis must be excluded. If, on the other hand, this error can be separated from the rest of the analysis, then—bearing in mind that exclusion is the exception not the rule, *In re Lipitor*, 892 F.3d at 631—the more appropriate course would be to permit Dr. Harold to testify on AAPA (using, of course, the *correct* quotation of the '864 Patent), and then to allow GWA, if it wishes, to cross-examine Dr. Harold on the extent to which the misquotation casts doubt on his credibility.

After a careful review of Dr. Harold's report, the Court is satisfied that the answer to the question, "how much of Dr. Harold's testimony is fatally tainted by the misquotation?" is, "not very much." Dr. Harold relies on multiple purported admissions of the patentee in arriving at his conclusions about anticipation and obviousness. Most of these purported admissions have nothing to do with the misquoted text, much less analytically depend on it. For instance, Dr. Harold contends that "[t]he applicant further admitted that precious metals are known components as the catalytic metal contained in CO to CO₂ promoters." (ECF No. 210-37 ¶ 88.) As another example, he states that the "[a]pplicant also admitted that an eggshell distribution of metal was known in catalyst particles as a term of art." (*Id.* ¶ 90.) GWA does not explain how the misquotation renders unreliable these statements about AAPA.

And to take another example, in the portion of the report entitled "AAPA in view of Espinoza Renders Obvious the Asserted Claims," Dr. Harold goes through, in a highly granular fashion, each term in the asserted claims. (ECF No. 210-37 ¶¶ 177–96.) The only portion of this analysis that depends on the misquotation is his discussion in paragraph 178 about how the "[t]he 'combustion' process is well known and admitted by the applicant to describe catalysts performing an oxidation reaction." The misquotation has no bearing on the rest of his analysis in this section, which instead focuses, word by word, on other portions of the claims of the '864 Patent. The same

pattern obtains in his discussion of “AAPA in view of Lin,” (*id.* ¶¶ 215–232), “AAPA in view of Witte,” (*id.* ¶¶ 256–276), “AAPA in view of Carlsson,” (*id.* ¶¶ 301–321), “AAPA in view of Schmidt,” (*id.* ¶¶ 346–368), “AAPA in view of Shyr,” (*id.* ¶¶ 392–412), and “AAPA in view of Baker,” (*id.* ¶¶ 438–462). In each instance, the misquotation casts doubt on the validity of Dr. Harold’s conclusion that the applicant admitted that the combustion process is well known, but it has no impact on the rest of the analysis.

As has become something of a pattern in this litigation, the parties spill much ink arguing the issue, but ultimately the solution is a simple one. Of course, Dr. Harold will not be permitted to present the misquotation of the ’864 Patent as if it were the true text. In addition, Dr. Harold will be barred from giving testimony to the effect that the patentee admitted that it was known that the noble metal in the center of a combustion promoter particle is inactive in the oxidation process. He will also be barred from testifying that the applicant admitted that the “the ‘combustion’ process is well known and admitted by the applicant to describe catalysts performing an oxidation reaction,” as he relied in part on the misquotation in reaching this conclusion and the Court cannot determine whether he would have reached the same conclusion without relying on the misquotation. Other than these restrictions, however, Dr. Harold generally will be permitted to testify about AAPA, as GWA does not otherwise challenge his credentials or the reliability of his analysis. (See ECF No. 242-1 at 8–10; ECF No. 250 at 12–14.)

ii. Testimony on Prosecution History Disclaimer

The next issue relates to GWA’s challenge to Dr. Harold’s testimony about prosecution history disclaimer. Specifically, GWA seeks to exclude Dr. Harold from testifying that GWA disclaimed any intent to patent an invention that lacks a method to prevent capillary effects. (ECF No. 242-1 at 11–12.) GWA chiefly relies on an argument that Dr. Harold’s analysis on this point

is based on a misleading interpretation of the patent prosecution history, but GWA also briefly notes—in a footnote—that Dr. Harold should not be permitted to testify on this subject at all, because prosecution history disclaimer is a legal issue for the Court to decide, not a jury question. (See *id.*)⁵

The Court agrees that Dr. Harold should be excluded from testifying about prosecution history disclaimer, because there is no question to present to the jury on the issue.⁶ The Court already discussed the prosecution history disclaimer issue in its summary judgment opinion. (ECF No. 231 at 51–54.) As the Court explained, Grace sought summary judgment of non-infringement on the grounds that GWA disavowed any method of manufacturing using single-step impregnation and/or any method that lacked a method to prevent capillary effects. (*Id.*) After reviewing the passage that Grace argued amounted to a disclaimer, and after considering the parties' positions on the matter, the Court concluded that Grace failed to show, by clear and convincing evidence, that GWA had disavowed or disclaimed methods using single-step impregnation or lacking a mechanism to prevent capillary effects. (*Id.*) This was so, the Court held, because the passage was “subject to at least two reasonable interpretations,” only one of which would amount to a disclaimer of the methods alleged practiced by the accused products. (*Id.* at 53.) And, as the Court explained, disclaimer applies “only if the patentee ‘clearly and unmistakably’ stated that the process was an essential part of the invention.” (*Id.* at 51 (citing *Cont'l Cirs. LLC v. Intel Corp.*, 915 F.3d 788, 799 (Fed. Cir. 2019).) “An ambiguous disavowal or disclaimer” will not suffice. (*Id.* (quoting *Schindler Elevator Corp. v. Otis Elevator Co.*, 593 F.3d 1275, 1285 (Fed. Cir. 2010).)

⁵ GWA expands on this latter argument in its reply brief. (See ECF No. 261 at 9–11.)

⁶ Because the Court determines that Dr. Harold’s testimony on this subject should be excluded on this ground, it does not reach—and expresses no opinion on—GWA’s argument that his testimony should also be excluded for mischaracterizing the prosecution history.

Strictly speaking, the Court’s holding in its summary judgment opinion was simply that Grace was not entitled to summary judgment in its favor on the question of prosecution history disclaimer. GWA had not cross-moved for summary judgment in *its* favor on the issue, and the Court saw no reason to award it summary judgment *sua sponte*. Nevertheless, although the Court has not awarded summary judgment on this issue to GWA, it is clear that there is no jury issue remaining on the question of disclaimer. The Court has concluded (and continues to hold) that the passage in question was ambiguous, and the Federal Circuit has made clear that ambiguous statements cannot meet the high bar of clear and unmistakable disclaimer.

The Court recognizes that some of the language in its earlier discussion of the issue suggested that there was a role for the jury to decide *which* of the two reasonable interpretations of the passage was correct. (ECF No. 231 at 53–54.) To the extent that the opinion suggested that a jury decides whether an ambiguous statement effected disclaimer, the Court was in error. *See Fed. R. Civ. P. 54(b)* (providing that a district court’s decisions “may be revised at any time” before final judgment). “Whether prosecution history disclaimer applies is a legal question [that the Federal Circuit] reviews *de novo*.” *Ecolab, Inc. v. FMC Corp.*, 569 F.3d 1335, 1342 (Fed. Cir.), *amended in part on other grounds on reh’g*, 366 F. App’x 154 (Fed. Cir. 2009). And “[i]f the challenged statements are ambiguous or amenable to multiple reasonable interpretations, prosecution disclaimer is not established.” *Tech. Props. Ltd. LLC v. Huawei Techs. Co.*, 849 F.3d 1349, 1358 (Fed. Cir. 2017). As the Federal Circuit has stated in the closely related context of prosecution history estoppel⁷:

⁷ As the Court has previously explained, the parties have not been entirely consistent as to whether this issue is properly better characterized as sounding in estoppel or in disavowal/disclaimer. (ECF No. 231 at 51 n.20.) But “[t]he exact classification of Grace’s argument is unimportant, because the test for argument-based estoppel is identical to that for disavowal: ‘To invoke argument-based estoppel, the prosecution

We have stated on numerous occasions that whether prosecution history estoppel applies . . . presents a question of law. The Supreme Court has recognized that, as a legal limitation on the application of the doctrine of equivalents, prosecution history estoppel is a matter to be determined by the court. Questions relating to the application and scope of prosecution history estoppel thus fall within the exclusive province of the court. Accordingly, the *determinations concerning whether the presumption of surrender has arisen and whether it has been rebutted are questions of law for the court, not a jury, to decide.*

Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., 344 F.3d 1359, 1367–68 (Fed. Cir. 2003) (emphasis added) (citations omitted); *accord iCeutica Pty Ltd. v. Lupin Ltd.*, Civ. No. MJG-17-0394, 2018 WL 656447, at *4 (D. Md. Feb. 1, 2018) (“Determination of prosecution history estoppel presents a question of law to be determined by the court, not a jury.”). Although this inquiry may involve subsidiary factual determinations, those, too, are for the Court to make. *Festo*, 344 F.3d at 1368 n.3.

Because this issue is one for the Court to decide, and because the Court has already held that the challenged statements cannot rise to the level of disclaimer or disavowal of all single-step impregnation techniques or of all techniques lacking a mechanism to prevent capillary effects, there is no valid reason to permit Dr. Harold to testify on the matter before the jury. His testimony on this issue cannot be helpful to the jury when the issue on which he would testify is one outside of the jury’s province altogether. *Cf. Sardis*, 10 F.4th at 281 (“Simply put, if an opinion is not relevant to a fact at issue, *Daubert* requires that it be excluded.”). Accordingly, Dr. Harold will be excluded from testifying on the question of prosecution history disclaimer/disavowal.

iii. Testimony on Statistics

Finally, GWA seeks to preclude Dr. Harold from presenting testimony on the subject of statistics. GWA bases its arguments on two contentions: first, that Dr. Harold himself admitted

history must evince a clear and unmistakable surrender of the subject matter.”” (*Id.* (citing *Power Integrations, Inc. v. Fairchild Semiconductor Int’l, Inc.*, 904 F.3d 965, 975 (Fed. Cir. 2018)).)

that he is not an expert in statistics because—although he uses statistical methods in his work—he does not consider himself to be an expert in the field, as he does not publish on it; and second, that his methodology is unreliable because it depends on an article intended for the “statistically challenged.” (ECF No. 242-1 at 14.)

GWA’s first argument is unavailing. Dr. Harold is generally qualified to testify on statistics on the basis of his “knowledge, skill, experience, training, or education.” Fed. R. Evid. 702. As Grace correctly notes, “although publishing in a peer-reviewed publication is often a hallmark of expert witness reliability, that hallmark is a guidepost, not a mandatory prerequisite to qualification as an expert.” *United States v. Young*, 916 F.3d 368, 380 (4th Cir. 2019). Indeed, a witness need not have formal academic credentials; “experience alone—or experience in conjunction with other knowledge, skill, training or education—”may suffice. *United States v. Wilson*, 484 F.3d 267, 274 (4th Cir. 2007) (citing Fed. R. Evid. 702 advisory committee’s note to 2000 amendments).

Dr. Harold holds a Ph.D. in chemical engineering from the University of Houston, where he has been a professor of chemical engineering for over twenty-five years. (See ECF No. 242-7 at 70–71.) He has published nearly two hundred peer reviewed articles on chemical engineering. (*Id.* at 73–82.) To be sure, neither his doctoral degree, nor his academic appointment, nor the nature of his publications, are about statistics *per se*. But, as Dr. Harold states in his deposition, his work “[i]ndirectly” involves statistics, because he is an “experimentalist” who “always worr[ies] about the statistics of [his] data.” (ECF No. 242-6 at 12.) He explains that he “can’t publish [his] papers without knowing or performing an error analysis on [his] data.” (*Id.*) So, although he has not “written any papers on statistics as a general subject[,] . . . statistical analysis of data is par for the course in [his] line of work.” (*Id.*) He describes statistics as “very important in problems that [he] studies,” and as a result he has a “working knowledge of statistics and

understanding data.” (*Id.* at 13–14.) Without such a knowledge, Dr. Harold states, he would not know how to “discriminate between good data and bad data.” (*Id.*) As such, he considers knowledge of statistics to be “just an expected expertise or subexpertise of a chemical engineer.” (*Id.*)

GWA seizes on a moment in his deposition where Dr. Harold says the following: “If I use my definition of expert as someone who publishes in statistical analysis, therefore I would not be an expert in that—in my self-imposed definition.” (ECF No. 242-6 at 15–16.) But Dr. Harold does not get to define who counts an expert under Rule 702. While he may *personally* equate expertise with publication, that is not the test under the laws of evidence. Publication is neither a necessary nor a sufficient criterion for qualifying an expert under Rule 702. *Daubert*, 509 U.S. at 593 (“Publication . . . is not a *sine qua non* of admissibility . . .”); *Young*, 916 F.3d at 380. Moreover, the Court considers the role that statistical analysis plays in the specific context of the issues to be presented to the jury. *See Kumho Tire*, 526 U.S. at 150 (“[T]he gatekeeping inquiry must be tied to the facts of a particular case.” (internal quotation marks and citation omitted)); *id.* at 156 (similar). Statistics are relevant here only insofar as they help the jury understand the core chemical-engineering issues at the center of the parties’ dispute. Thus, what is most helpful to the jury is not necessarily the testimony of a pure statistician, but rather someone with experience in and knowledge of applying statistical methods to chemical-engineering problems—in other words, someone just like Dr. Harold.

Ultimately, the fact that Dr. Harold says that he is not an expert in statistics on the basis of his “self-imposed definition” of the term, while perhaps *relevant* to the inquiry of whether he has the requisite “knowledge, skill, experience, training, or education,” *see* Fed. R. Evid. 702, is certainly not *dispositive* of the question. The alternative would be absurd. If GWA were correct,

then evidence law would contain the anomaly that otherwise-qualified expert witnesses may be barred from testifying purely because of their own modesty or idiosyncratic understanding of the word “expert.” Federal juries would never hear from the brilliant but humble.

All that said, while Dr. Harold is *generally* qualified to testify on statistical matters, Grace still must demonstrate that the specific testimony he would offer to the jury is based on sufficient facts and data and is the result of reliable principles and methods applied reliably to the facts of this case. Fed. R. Evid. 702(c)–(d). Grace has satisfied these requirements.

Importantly, on this subject of statistics, Dr. Harold will be testifying as a rebuttal expert—*i.e.*, his testimony on this matter is offered solely to contradict the anticipated testimony of GWA’s experts. “When offering rebuttal expert testimony, the expert has no burden to produce models or methods of their own; they need only attack those of the opposing party’s experts.” *Finley Alexander Wealth Mgmt., LLC v. M&O Mktg., Inc.*, Civ. No. PJM-19-1312, 2024 WL 1640997, at *5 (D. Md. Apr. 16, 2024) (alteration omitted) (quoting *EarthKind, LLC v. Lebermuth Co.*, Civ. No. 19-00051-KDB-DCK, 2021 WL 2226492, at *3 (W.D.N.C. June 2, 2021)). As one court has explained:

The task of a rebuttal expert is different from that of an affirmative expert. A rebuttal expert, by nature, criticizes the methodology and/or opinions of another. There is no requirement that a rebuttal expert himself offer a competing analysis; his opinions may properly concern criticizing that presented by another party. Rebuttal experts, therefore, have a less demanding task because they have no burden to produce models or methods of their own; they need only attack those of plaintiffs’ expert.

In re Aluminum Warehousing Antitrust Litig., 336 F.R.D. 5, 29 (S.D.N.Y. 2020) (cleaned up). Still, even rebuttal experts must satisfy the basic reliability requirements of *Daubert*. *In re Generic Pharms. Pricing Antitrust Litig.*, Civ. No. 16-CB-27242, 2024 WL 4980784, at *14 (E.D. Pa. Dec. 3, 2024), *reconsidered in part on other grounds*, 2025 WL 478178 (E.D. Pa. Feb. 12, 2025).

GWA makes much of the fact that Dr. Harold cites several times to an article titled “How

to choose a sample size (for the statistically challenged).” Piroska Bisits Bullen, *How to choose a sample size (for the statistically challenged)*, Tools4dev, <https://tools4dev.org/resources/how-to-choose-a-sample-size/> [https://perma.cc/WU9K-QBUJ] (the “Dr. Bullen article”). His choice to cite to this article was perhaps imprudent. But he cites to the article for only the propositions that “different statisticians have different rationales in picking the sample size” and that “exemplary and conventional statistical analysis customarily includes . . . an error bar” indicating the margin of error in a statistical measurement. (ECF No. 242-7 ¶¶ 59, 62.) GWA does not contest the underlying accuracy of either statement, although it does contend that the citation to the Dr. Bullen article is misplaced because that article discusses sampling of human populations, not inanimate objects. This matters because, as GWA notes, humans might not respond to a survey, but “there cannot be a non-response rate for inanimate catalyst particles.” (ECF No. 242-1 at 15 (emphasis deleted).)

The Court agrees with GWA, to a point. The use of the table in Dr. Harold’s report, which he took from the Dr. Bullen article, is misleading in the context of this case, as it clearly relates to sampling of human populations, which raises distinct statistical issues very different from the ones raised here. (ECF No. 242-7 ¶ 62.) Thus, the Court will exclude Dr. Harold from testifying as to this chart. But, otherwise, his testimony is sufficiently reliable and grounded in facts to present to the jury. His testimony is mainly in the nature of presenting his views on the methods used by the Plaintiffs’ experts and in forming his own opinions. His discussion is lucid, plausible, and informed by his extensive experience in applying statistical methods to chemical engineering issues. Dr. Harold does not propose his own unsupported theories but instead uses his underlying statistical knowledge and experience to attempt to poke holes in the Plaintiffs’ analysis by focusing on (what he maintains) are flawed assumptions (such as the nature of the sample being analyzed)

or discordant data. (See generally *id.* ¶¶ 40–66.) This is well within the appropriate scope of a rebuttal expert.

2. Testimony of Ms. Schenk

Under Section 35(a) of the Lanham Act, once the plaintiff has established liability in a false advertising action, it is generally entitled to recover (1) the defendant's profits derived from the false advertising, (2) any damages it suffered, and (3) the costs of the action. 15 U.S.C. § 1117(a). The statute provides that “[i]n assessing profits the plaintiff shall be required to prove defendant's sales only; defendant must prove all elements of cost or deduction.” *Id.* Thus, by the terms of the statute, “the burden is on the defendant, not the plaintiff, to prove the elements of cost or deduction claimed.” *Entrepreneur Media, Inc. v. JMD Ent. Grp.*, 958 F. Supp. 2d 588, 597 (D. Md. 2013) (cleaned up).⁸

Here, Grace intends to introduce evidence of overhead expenses to offset some of the profits it would otherwise have to pay in the event it is found liable for false advertising with respect to its Optimized CPP product line. Although GWA presents its arguments in the form of a *Daubert* motion, the issue has nothing to do with Ms. Schenk's qualification or the general reliability of her analysis (both of which are undisputed). Instead, GWA essentially argues that indirect evidence of overhead expenses based on companywide overhead costs is *per se* inadmissible as a matter of law. (ECF No. 242-1 at 17–20.)

On this, the Court disagrees. In determining which costs a defendant is entitled to deduct, “there is no hard and fast rule . . . ; in each case the trial court must determine which elements of cost or loss it is fair to allow defendant to offset.” *Hosp. Int'l v. Mahtani*, Civ. No. 97-87, 1998

⁸ Most of the cases on this topic involve copyright infringement, rather than false advertising. By its terms, 15 U.S.C. § 1117(a) applies equally to both types of unlawful behavior, and accordingly the Court sees no reason why copyright cases would be inapposite in this false advertising action.

WL 35296447, at *9 (M.D.N.C. Aug. 3, 1998) (quoting *Jones Apparel Grp. v. Steinman*, 466 F. Supp. 560, 563 n.4 (E.D. Pa. 1979)). Generally, courts permit defendants to deduct “only marginal costs (*i.e.*, those costs which the infringer would not have incurred but for the sale of the infringing goods or services).” *Id.* Courts have not permitted defendants to deduct overhead expenses unless the defendant “satisf[ies] its burden of providing a sufficient nexus between each claimed expense and the sale of the unlawful goods.” *Id.* at *22.

Here, Grace’s damages expert, Ms. Schenk, arrived at an estimate of Grace’s overhead expenses by “calculat[ing] the relevant [overhead] expenses for . . . Optimized CPP sales based on the proportion of [overhead] expenses to Grace’s net sales, as reflected in the company’s income statements.” (ECF No. 242-11 ¶ 171.) Grace represents—and GWA does not dispute—that it does not track overhead expenses “at a product level in the ordinary course of Grace’s business.” (ECF No. 210-36 at 55.)

It is true that courts have barred defendants from introducing evidence of overhead expenses when the defendants failed to show that those expenses were adequately tied to the actual expenses incurred from selling the infringing goods or service. For example, in a Second Circuit trademark infringement case, the court barred the defendant from deducting overhead expenses, which the defendant obtained by offsetting its total overhead by the percentage of net sales derived from the infringing products. *Manhattan Indus., Inc. v. Sweater Bee by Banff, Ltd.*, 885 F.2d 1, 8 (2d Cir. 1989). At first blush, then, this case appears highly favorable to GWA. But a closer look reveals that *Manhattan Industries* is distinguishable. For one, the court expressly recognized that “[t]here is some support for the proposition that a party may approximate overhead in the absence of reliable data pertaining to actual overhead.” *Id.* (first citing *Frank Music Corp. v. Metro-Goldwyn-Mayer, Inc.*, 772 F.2d 505, 516 (9th Cir. 1985), and then citing *Kamar Int’l, Inc. v. Russ*

Berrie & Co., 752 F.2d 1326, 1333 (9th Cir. 1984)). More importantly, the defendant in *Manhattan Industries* failed to demonstrate that more reliable data were unavailable before seeking to derive overhead costs from a companywide estimate. The court held that “[e]stimates should not be used unless such a showing has been made.” *Id.* Here, by contrast, as mentioned above, it is undisputed that Grace does not have overhead data broken down by individual product line. Thus, an estimate based on companywide data is likely the best evidence available. *See Headwater Rsch. LLC v. Samsung Elecs. Co.*, Civ. No. 2:22-00422-JRG-RSP, 2024 WL 4712953, at *6 (E.D. Tex. Nov. 7, 2024) (While [the expert’s] apportionment opinions on SG&A and R&D adjustments are derived from company-wide values rather than something more precise, it is within the purview of an expert to opine from the best available evidence rather than perfect evidence. The Court sees no reason to find company-wide valuations for SG&A and R&D cannot inform an expert as to a particular business unit.”).

As Grace correctly observes, numerous courts have approved the use of companywide overhead costs to arrive at an estimate of allowable deductions in analogous circumstances. *See, e.g., In Design v. K-Mart Apparel Corp.*, 13 F.3d 559, 566 (2d Cir. 1994) (collecting cases), abrogated in part on other grounds by *Fogerty v. Fantasy, Inc.*, 510 U.S. 517 (1994). GWA protests that these cases involve Section 504 of the Copyright Act, not Section 35 of the Lanham Act. (ECF No. 261 at 18.) True enough. But the Court views this as a distinction without a difference. The relevant section of the Copyright Act provides that “[i]n establishing the infringer’s profits, the copyright owner is required to present proof only of the infringer’s gross revenue, and the infringer is required to prove his or her deductible expenses and the elements of profit attributable to factors other than the copyrighted work.” 17 U.S.C. § 504(b). The statutes are not word-for-word identical, but GWA does not point to (and the Court cannot discern) any

meaningful difference between the Lanham Act’s requirement that a “defendant must prove all elements of cost or deduction,” 15 U.S.C. § 1117(a), and the Copyright Act’s statement that the defendant “is required to prove his or her deductible expenses,” 17 U.S.C. § 504(b). Given the similarity in language—and in the absence of any express direction in either statute as to how such deductions must be proved—it would be odd if courts imposed on defendants a higher evidentiary burden in the false advertising and trademark context than in the copyright context.

There is another consideration guiding the Court’s decision not to exclude Ms. Schenk’s testimony. Courts have justifiably expressed reluctance to exclude evidence of overhead costs altogether, given the inevitability that some overhead costs were necessarily incurred by the defendant, and would have been incurred by the plaintiffs had they been the ones to make the sale. Given this reality, excluding all evidence of deductions would produce an unfair windfall for plaintiffs, as it would effectively allow them to earn a 100 percent profit margin on every one of a defendant’s sales. *See Oracle Am., Inc. v. Google Inc.*, Civ. No. 10-03561-WHA, 2012 WL 4017808, at *5 (N.D. Cal. Apr. 10, 2012) (citing *Cream Records, Inc. v. Jos. Schlitz Brewing Co.*, 754 F.2d 826, 828–29 (9th Cir. 1985)). Furthermore, the leeway that the Court accords to a defendant in presenting evidence of overhead costs is fair, given that courts regularly permit plaintiffs to establish a defendant’s profits by extrapolating from indirect, circumstantial evidence. *See, e.g., Surf’s Up, LLC v. Rahim*, Civ. No. 4:14-4706-BHH-KDW, 2017 WL 9287000, at *7 (D.S.C. Nov. 14, 2017), *report and recommendation adopted*, 2017 WL 6032340 (D.S.C. Dec. 5, 2017); *Choice Hotels Int’l, Inc. v. Fisher*, Civ. No. 2:13-23, 2015 WL 12748029, at *7 (N.D. W. Va. Apr. 1, 2015). If plaintiffs are permitted to rely on inevitably imprecise guesswork in calculating profits, it is only fair that defendants be accorded the same flexibility.

Ultimately, the Court is satisfied that Ms. Schenk’s estimate of overhead expenses is a

rational way of estimating the deductions that Grace may be entitled to in the event that it is found liable for damages for false advertising. Beyond pointing to the bare fact that Ms. Schenk bases her estimate of overhead expenses on companywide data, GWA does not otherwise take issue with the reliability of her analysis or the adequacy of her credentials. Thus, the Court sees no basis to bar Ms. Schenk from testifying under *Daubert* and Rule 702. To the extent that GWA contends that Ms. Schenk's analysis may be inaccurate or incomplete, those are issues that go to the weight, not the admissibility, of her testimony.

On this issue, the Court pauses to make one final observation. GWA's motion on this matter will be denied, and Grace will be permitted to present evidence of deductions by discounting companywide overhead expenses by the percentage of sales attributable to the allegedly false advertising. But to be entitled to claim these deductions, Grace cannot rely *solely* on such evidence. At trial, Grace must also produce at least some evidence from which a jury could find a "nexus between each expense claimed and the sales of the unlawful goods." *Manhattan Indus.*, 885 F.2d at 8. This evidence need not come in the form of a direct link between each sale and the expenses associated with that sale, but there must at least be evidence that Grace incurred its typical overhead costs in selling Optimized CPP, or that indicates that the overhead expenses associated with the sales of Optimized CPP were broadly representative of overhead expenses companywide. *See Frank Music*, 772 F.2d at 516 ("[T]he defendant bears the burden of explaining, at least in general terms, how claimed overhead actually contributed to the production of the infringing work.").

B. Defendant's Motion to Exclude

1. Testimony of Mr. Tregillis

GWA plans to call Mr. Tregillis as an expert witness on damages. One matter on which

Mr. Tregillis plans to testify is the unjust enrichment that Grace allegedly enjoyed from its sales of Optimized CPP. In his report, Mr. Tregillis assumes that Grace will be found liable for false advertising, and he arrives at his total damages estimate by first breaking down Grace's sales of Optimized CPP by each of the refineries that purchased Optimized CPP over the relevant time period, then adding up all of those sales to reach a total figure. (*See generally* ECF Nos. 240-2; 254-1.)

In its Motion to Exclude, Grace does not challenge Mr. Tregillis's qualifications, nor does it mount any broad attack on his methodology or the conclusions he reaches. Instead, Grace seeks to exclude only a portion of his testimony that relates to profits attributable to Grace's sales of Optimized CPP to six specific refineries. With respect to these six refineries,⁹ Grace argues, Mr. Tregillis did not rely on "any evidence that the advertisements at issue impacted their purchasing decisions." (ECF No. 239 at 10.) For example, Mr. Tregillis included in his report profits associated with sales of Optimized CPP to a Chilean refinery called "ENAP," but conceded in his deposition that he was not aware of any specific evidence showing that allegedly false information relating to a trial at a Valero facility was provided to ENAP. (ECF No. 239-2 at 8.) With respect to profits associated with these six refineries, then, Grace argues that "Mr. Tregillis fails to offer any facts or data as to causation," and therefore that his testimony on this matter is inadmissible under Rule 702(b). (ECF No. 239 at 10.)

In support of its Motion to Exclude, Grace cites to the proposition that, in a false advertising action, a plaintiff's expert cannot "assume that every sale defendant made was attributable to the allegedly false statement." *Verisign, Inc. v. XYZ.COM LLC*, 848 F.3d 292, 301 (4th Cir. 2017)

⁹ These refineries are "the CHS refinery in Laurel, MT; the Citgo refinery in Lake Charles, LA; the Citgo refinery in Lemont, IL; the HF Sinclair refinery in Tulsa, OK; the Chalmette Refining refinery in Chalmette, LA; and the ENAP refinery in Talcahuano, Chile." (ECF No. 239 at 10 n.3.)

(cleaned up) (quoting *PBM Prods., LLC v. Mead Johnson & Co.*, 639 F.3d 111, 122 (4th Cir. 2011)). However, Grace takes this statement out of context. The court in *Verisign* was discussing the burden on a plaintiff to establish that it suffered “actual damages,” one of the essential elements of a Lanham Act claim. *Id.* at 300–301. But here, Grace does not contest—and did not contest at the summary judgment stage—that there is at least a jury-triable issue on whether GWA suffered “actual damages” from Grace’s actions (assuming the other elements of the Lanham Act claim are established). The statute is clear that once a plaintiff establishes a false-advertising violation under 15 U.S.C. § 1125(a), then the plaintiff is required only to further prove the “defendant’s sales”; the burden is on the defendant to show that certain sales were not attributable to the false advertising. 15 U.S.C. § 1117(a). In other words, after the plaintiff establishes the defendant’s “infringing revenues,” the burden shifts to the defendant “to present revenues unrelated to the infringement and the costs that should be deducted.” *Dewberry Eng’rs Inc. v. Dewberry Grp.*, 77 F.4th 265, 290 (4th Cir. 2023), *vacated and remanded on other grounds*, 604 U.S. ___, 145 S. Ct. 681 (2025). This burden-shifting framework means that the defendant has the burden of deducting “any portion of sales that was not due to the allegedly false advertising.” *Rexall Sundown, Inc. v. Perrigo Co.*, 707 F. Supp. 2d 357, 359 (E.D.N.Y. 2010).

Here, Mr. Tregillis does not intend to testify on the question of whether Grace’s advertisements caused actual damages to GWA. Instead, his role is limited to opining on the profits attributable to its sales of Optimized CPP, but only on the assumption that liability—including the “actual damages” element—has been established. Presumably, GWA has *other* evidence beyond Mr. Tregillis’s testimony it intends to offer at trial to establish that it *actually* suffered damages, as

is required for a Lanham Act claim (if not, then its Lanham Act claim is likely doomed).¹⁰ Thus, Grace's argument that Mr. Tregillis has not shown that the specific refineries received the false advertisements is "a bit of red herring," *Multiple Energy Techs., LLC v. Under Armour, Inc.*, Civ. No. 2:20-664-NR, 2025 WL 82328, at *3 (W.D. Pa. Jan. 13, 2025), as "it is perfectly permissible for an expert to assume liability (of which causation is an element) and simply focus on the issue of damages," *Vir2us, Inc. v. Sophos Inc.*, Civ. No. 19-18, 2025 WL 299392, at *8 (E.D. Va. Jan. 24, 2025) (cleaned up).

To be sure, all of this is not to say that a damages expert has free rein to testify about every possible source of profit under the sun. Although the expert need not have conclusive proof of causation, the expert must have a reasonable basis for assuming that the profits are attributable to the allegedly unlawful conduct. *See Globus Med., Inc. v. Jamison*, Civ. No. 22-282, 2024 WL 4711947, at *9 (E.D. Va. Nov. 7, 2024) ("A damages expert's report may be excluded due to a failure to establish causation when that testimony is based on faulty assumptions that are directly disputed by the evidence, or when the court concludes that there is 'simply too great an analytical gap between the data and the opinion proffered.'") (quoting *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997))). But exclusion of a damages expert for failure to show causation is limited to cases of "extreme disconnect between the facts of the case and assumptions made by experts preparing testimony." *Id.* Here, there was no such disconnect, as Mr. Tregillis could reasonably have assumed that Grace sent advertisements to the six refineries at issue given the existence of Grace's broader marketing campaign, which was targeted toward a small, known set of consumers. Moreover, to the extent that Mr. Tregillis's failure to cite to specific evidence calls the credibility

¹⁰ Given how vigorously the parties have litigated this case, the Court assumes that, if GWA was unable to unearth any evidence during discovery that could establish the actual-damages element, then Grace would have moved for summary judgment on that issue.

of his analysis into question, that it an appropriate subject for cross-examination, not exclusion.

Because Grace—not GWA—has the burden of proving any sales that were “not due to the allegedly false advertising,” *Rexall*, 707 F. Supp. 2d at 359, and because Grace has not generally challenged Mr. Tregillis’s qualifications or methodology, Mr. Tregillis will be permitted to testify as to Grace’s profits attributable to Optimized CPP.¹¹

2. Testimony of Dr. Ehrhardt

Finally, the Court turns to Grace’s request that it preclude GWA’s putative statistics expert, Dr. Ehrhardt, from testifying as to the statistical significance of GWA’s testing of a sample of Grace’s combustion promoter products. In particular, Grace contends that Dr. Ehrhardt impermissibly relied on a “rule of thumb” called the “Rule of 12.”

At a high level, the Rule of 12 provides that, when surveying a population, and under certain conditions, one generally needs to only look at twelve samples to obtain a statistically representative result. More specifically, as stated in *Statistical Rules of Thumb* by Dr. Gerald van Belle—the book that Dr. Ehrhardt cites in his report—it provides that “[t]he width of a confidence interval, involving estimation of variability and sample size, decreases rapidly until 12

¹¹ The briefing raises another issue that ultimately buttresses the Court’s conclusion on this score. GWA contends that other evidence produced by Grace in discovery shows that the six refineries *did* in fact receive the challenged advertisements, even if Mr. Tregillis did not rely on this evidence in his report. (ECF No. 253 at 11–14.) Grace counters that this evidence does not actually show that the advertisements caused the sales, (ECF No. 258 at 10–11), and that Mr. Tregillis cannot rely on this evidence now in any event, as he was required under Federal Rule of Civil Procedure 26(a)(2)(B) to provide a “complete statement” of all facts and data he relied on in making his report, and that he did not timely supplement his report under Rule 26(e), (*Id.*).

Under Rule 37(c)(1), a party is generally prohibited from relying at trial on evidence that it did not disclose during discovery. However, the Court may permit the presentation of such evidence if delay is either substantially justified or harmless. *S. States Rack & Fixture, Inc. v. Sherwin-Williams Co.*, 318 F.3d 592, 596 (4th Cir. 2003). Here, Mr. Tregillis’s failure to cite to evidence showing that the six refineries received the advertisements is not substantially justified, but it is harmless. The “basic purpose of Rule 37(c)(1)” is to “prevent[] surprise and prejudice to the opposing party.” *Id.* Here, Grace cannot fairly complain of being surprised or prejudiced by evidence that *Grace itself* provided in discovery, especially since the evidence consists of statements that it itself made.

observations are reached and then decreases less rapidly.” (ECF No. 239-6 at 21.) A confidence interval is “a limit above or below or a range around the sample mean, beyond which the true population is unlikely to fall.” *Perez v. Mountaire Farms, Inc.*, 650 F.3d 350, 362 n.4 (4th Cir. 2011) (citing D. Barnes & J. Conley, *Statistical Evidence in Litigation*, § 3.15 at 107 (1986)).¹²

Dr. Ehrhardt uses the van Belle book to support the following proposition:

There are general guidelines/recommendations for the minimum number of samples required for assuming congruence between subsample and source population. Quantitative modeling suggests that when a sample size reaches more than 12 observations, the distribution of measurements from the subsample does not deviate markedly from measurements of the source population (van Belle, 2008). Because the number [of] particles analyzed for this report ranged between 27 and 30, the distributional characteristics of the subsample should be accurate approximations of the source population of particles.

(ECF No. 253-2 at 13.)

Grace makes much of the fact that the book to which Dr. Ehrhardt cited for the Rule of 12 denominates that proposition as a “rule of thumb.” Grace cites to a pair of Federal Circuit cases that have rejected the use of “rules of thumb” in calculating the damages for patent infringement. *See Uniloc USA, Inc. v. Microsoft Corp.*, 632 F.3d 1292 (Fed. Cir. 2011); *VirnetX, Inc. v. Cisco Sys., Inc.*, 767 F.3d 1308 (Fed. Cir. 2014). Both cases are distinguishable. In *Uniloc*, the Federal Circuit rejected the “25% rule of thumb,” which was “used to approximate the reasonable royalty rate that the manufacturer of a patented product would be willing to offer to pay to the patentee during a hypothetical negotiation.” 632 F.3d at 1312. The court explained that damages experts relying on this rule could not withstand scrutiny under *Daubert*, because the rule “does not say

¹² For example, “[i]f a study has 95% confidence interval calculated, then this means that if the study was repeated multiple times with samples from the whole population and the confidence intervals were calculated for each of those repeated studies, then the true value would lie within the calculated confidence intervals 95% of the time.” *Common Terms & Equations—Confidence Intervals*, Nat’l Lib. of Med., <https://www.nlm.nih.gov/oet/ed/stats/02-950.html> [<https://perma.cc/ST4T-J3MY>].

anything about a particular hypothetical negotiation or reasonable royalty involving any particular technology, industry, or party.” *Id.* at 1317. Because the rule failed to take into account the inevitability that actual royalty negotiations would vary widely depending on factors such as the relative market power of the parties, the technology and industry at issue, and the importance or value of the patent, the court described it as an “arbitrary, general rule, unrelated to the facts of th[e] case.” *Id.* at 1318. For similar reasons, the court in *VirnetX* rejected the use of the “Nash Bargaining Solution,” which assumed a fifty-fifty royalty split, because it was based on a mathematical theorem that was not tied to the specific facts of negotiations in any given case. 767 F.3d at 1332.

Neither *Uniloc* nor *VirnetX* suggests that the law contains a *per se* prohibition on experts relying on ideas cast as “rules of thumb.” Instead, both have to do with the unique context of calculating royalties in patent infringement cases, which necessarily involves an individualized inquiry into a hypothetical negotiation between the specific parties in a case. In short, both cases dealt with the problem of assumptions about negotiations that “made too crude a generalization about a vastly more complicated world.” *VirnetX*, 767 F.3d at 1332.

The Rule of 12, at least as applied to the facts of this case, is not the kind of rule of thumb proscribed in *Uniloc* or *VirnetX*. It is based on statistical calculations that this Court is no position to evaluate but that seem at least facially plausible, and the text cited for the rule is written by a reputable author in the field.¹³ Of course, this alone is not enough. Even the most unimpeachably sound theory “must be tied to the relevant facts and circumstances of the particular case at issue,”

¹³ Pursuant to Rule 201(b)(2), the Court takes judicial notice of the fact that the author of the text holds a Ph.D. in mathematics and is an emeritus professor of biostatistics at the University of Washington. *Gerald van Belle*, Univ. of Washington Sch. of Pub. Health, <https://www.biostat.washington.edu/people/gerald-van-belle> [<https://perma.cc/CBM9-EFB6>].

Uniloc, 632 F.3d at 1318—a requirement the Federal Circuit used to reject the Nash Bargaining Theorem, even though it was derived from analysis performed by a Nobel-prize winning mathematician. *See VirnetX*, 767 F.3d at 1325. But it is easier for the Rule of 12 to meet that requirement here than it is for the Nash Bargaining Solution to be validly applied to any given hypothetical royalty negotiation. That is so because the Rule of 12 is a rule about statistics and the laws of probability as such, and it is here applied to a straightforward statistical problem of measuring a sample of inanimate particles. *See* ECF No. 253-2 ¶ 17 (“The statistics employed for this analysis, test statistics for equality of means and medians, are some of the most foundational in data analysis for comparing samples. In fact, comparing such metrics calculated from a sample embodies the very definition of statistics, ‘drawing of inferences about a body of data when only a part of the data is observed.’” (quoting Wayne Daniel, *Biostatistics: A Foundation for Analysis in the Health Sciences* (7th ed. 1999).) Its application does not depend on the vagaries of a hypothetical business negotiation. This case is unlike those in which experts have sought to apply the abstract niceties of the Nash Bargaining Solution to the messy world of human relations, without ensuring that the theoretical prerequisites for the Nash Bargaining Solution have been met.

Beyond arguing that the Rule of 12 is *per se* unreliable, Grace contends that the use of the Rule of 12 depends on assuming that certain preconditions about the sample to be measured are met, and that Dr. Ehrhardt did not explain whether these preconditions in fact obtained. (ECF No. 239 at 13–15.) In particular, Grace argues that, according to the terms of van Belle, the Rule of 12 applies only when (1) “the sample came from a normal population,” (2) “the sample standard deviation has an associated pivotal variable, the *t*-statistic,” and (3) the sample has “*n*–1 degrees of freedom.” (ECF No. 239 at 14–15 (quoting ECF No. 239-6 at 21–22).) The Court finds, however, that Dr. Ehrhardt’s report adequately demonstrates the basis for him to apply the Rule of 12. He

explains that he performed one version of the analysis in which he ran a “t-test” assuming that the observations were “normally distributed,” ran two other tests without making “strict distributional assumptions,” and then assessed all three tests, given that “measurements or observations rarely show unambiguously normal distributions nor do they unambiguously satisfy the assumptions of parametric statistical tests.” (ECF No. 253-2 ¶¶ 18–19.) As for the “ $n-1$ degrees of freedom” requirement, van Belle does not indicate that this is a precondition for application of the Rule of 12; rather, the $n-1$ reference appears only in a graph that is described as an “illustration” of the principle. (ECF No. 239-6 at 21–22.)

Fundamentally, Grace seems to think it is inherently preposterous to suppose that anyone could arrive at a conclusion about the property of a batch containing possibly a “quadrillion” particles from an observation of only thirty such particles. (ECF No. 239 at 5.) Certainly, the disparity between the small number of particles measured and the large number of particles in a batch is an issue to which Grace is entitled to draw the jury’s attention on cross-examination. But the Court has no basis for concluding that the use of the Rule of 12, as applied to the facts of this case, is inherently unreliable. Dr. Ehrhardt indicates that the individual particles tested were randomly chosen from a well-mixed, representative sample of the batch of Optimized CPP.¹⁴ (ECF

¹⁴ The randomness of the initial selection of particles to test distinguishes this case from the cases cited by Grace for the proposition that “courts have held that even larger sample sizes were insufficient to determine the properties of even smaller populations.” (ECF No. 239 at 15.) As GWA correctly notes, those cases all have to do with testing of product defects, in which the products tested were already likelier than average to be defective. The courts therefore had little confidence that the testing was representative of the prevalence of defects in the universe of the products as a whole. *See In re Pella Corp. Architect & Designer Series Windows Mktg., Sales Pracs. & Prods. Liab. Litig.*, 214 F. Supp. 3d 478, 493 (D.S.C. 2016) (expressing concern about “selection bias” because the windows tested were “almost exclusively” owned by the named plaintiffs who “certainly felt that *something* was wrong with their [w]indows”); *Varner v. Dometic Corp.*, Civ. No. 16-22482, 2022 WL 2307025, at *3 (S.D. Fla. Feb. 2, 2022), *objections overruled sub nom. Papasan v. Dometic Corp.*, 2022 WL 1222817 (S.D. Fla. Apr. 26, 2022) (expert testimony on allegedly defective cooling units unreliable when the testing was limited to “a small sample of already-failed cooling units”); *Grodzitsky v. Am. Honda Motor Co.*, Civ. No. 12-001142-SVW-PLA, 2017 WL 8943159, at *4 (C.D. Cal. Oct. 30, 2017), *aff’d*, 957 F.3d 979 (9th Cir. 2020) (testing of twenty-six products

No. 253-2 ¶ 26.) Moreover, Dr. Ehrhardt observes that, empirically, the average results of the test showed little change after the thirteenth particle was added, thus indicating that the “population statistics are unlikely to change in any significant manner if data from additional particles is collected.” (*Id.* ¶ 28.)¹⁵

Finally, the results that Dr. Ehrhardt obtained were expressed with a high degree of statistical confidence, as expressed by a p-value of less than 0.001. (ECF No. 253-2 ¶¶ 23–25.) “A p-value represents the probability that an observed positive association could result from random error even if no association were in fact present.” *In re Lipitor*, 892 F.3d at 641 (citation omitted). For example, a p-value of 0.05 (often used as the threshold for statistical significance in the sciences) means that the odds that the result reached is a fluke, rather than the result of a true association, is five percent. *Id.* Here, the p-value of 0.001 means that the likelihood of observing the same (or greater) strength of association, when in fact no such association exists, is a mere 0.1 percent, or a one-in-a-thousand chance. A strong p-value score or finding of statistical significance is not a “get-out-of-*Daubert*-free card,” but it does bear on the question of reliability. *Id.* And in this case, it is but one of several considerations that indicate that Dr. Ehrhardt’s testimony is admissible under *Daubert* and Rule 702.

It is important to observe that Grace does not challenge Dr. Ehrhardt’s credentials or any aspect of his analysis other than the size of the sample that he analyzed. On the narrow issue

out of 441,600 unreliable when eleven of the twenty-six products tested were supplied directly by the plaintiffs, and the rest were chosen arbitrarily).

¹⁵ Grace makes much of the fact that the results changed between the twelfth and thirteenth particles, arguing that this refutes the Rule of 12 altogether. However, at most, the empirical data would simply support a “Rule of 13.” Even Grace does not contest that the results did not meaningfully change *after* the thirteenth particle. So, assuming that the data indicate that one must actually test *thirteen* particles rather than twelve to get a meaningful sample size, that would have little bearing on the reliability of the testing in this case, as Dr. Ehrhardt analyzed more than twice as many particles as that—and, again, the analysis did not change meaningfully after the thirteenth.

presented by Grace's Motion to Exclude, the Court is satisfied that Dr. Ehrhardt applied reliable and well-known statistical methods to arrive at the conclusion that, "[b]ecause the number [of] particles analyzed for this report ranged between 27 and 30, the distributional characteristics of the subsample should be accurate approximations of the source population of particles," (ECF No. 253-2 at 13). From this statement, it should be apparent that the Court's holding in this regard is not a broad one. The Court makes no determination as to whether Dr. Ehrhardt's analysis is ultimately correct, nor does it decide whether this testimony could suffice, on its own, to allow a reasonable jury to conclude that "each" (as defined in the Court's Claim Construction Order, (ECF No. 110 at 42)) of Grace's Optimized CPP particles conforms to the '864 Patent claim limitations.

IV. CONCLUSION

For the reasons stated herein, the Court will grant in part and deny in part GWA's Motion to Exclude, and it will deny in its entirety Grace's Motion to Exclude. A separate order will issue.

DATED this 9 day of April, 2025.

BY THE COURT:



James K. Bredar
United States District Judge